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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,511	06/16/2006	Tsutomu Suzuki	500.46232X00	1325

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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10/01/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	Application No. 10/583,511	Applicant(s) SUZUKI ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/2006 and 4/22/2008</u> .                                 | 6) <input type="checkbox"/> Other: ____.                          |

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

2. The information disclosure statements filed 6/16/2006 and 4/22/2008 have been considered and made of record.

***Claim Objections***

3. Claim 6 is objected to because of the following informalities: Claim 6, line 4, it appears that "pint" should be --point--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8, line 8, "the bactericide-impregnated membrane" lacks antecedent basis. Note the claim uses the terminology "member" rather than "membrane" at line 6.

Claim 8 is indefinite because the claim fails to set forth structural cooperation between the positively recited elements of claim 1 and the previously recited structural elements of the device. As a result, it is not clear how the elements of claim 8 cooperate with the elements of claims 1, 2 or 5.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 9, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Masao et al.(JP 58-155087).

With respect to claim 1, the reference of Masao et al. discloses a cell culture device that includes an incubator means (4); a heat insulation box (3) which maintains the incubator means (4) at a given temperature; a driving device (6) for rotatively moving the incubation device (4) in the heat insulation box (3); a medicine supply device (8) positioned outside the box (3); a wastewater discharge device (7) positioned outside the box (3); and a culture observation device (14) for observing the cells from outside the box (3).

With respect to claim 2, the medicine supply device (8) includes pump, valve and flexible tube (74,76) members.

With respect to claim 3, the incubator device (4) is a Petri dish which includes a smooth central part and is made of a transparent and non-toxic material.

With respect to claim 9, the device is considered to inherently includes a gas bomb since the box (3) is supplied and/or maintained at 5% carbon dioxide concentration (See the English language abstract).

With respect to claim 10, the medicine supply device (8) is structurally capable of controlling the amount of liquid supplied.

With respect to claims 13 and 14, the culture device of Masao et al. includes a control device (13) which controls the operation of the device and is structurally capable of interfacing with other control devices.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masao et al.(JP 58-155087) in view of Buterbaugh (US 3,649,463).

The reference of Masao et al. has been discussed above.

While the reference discloses the use of a Petri dish (4), the reference is silent with respect to the material of construction.

The reference of Buterbaugh is cited to evidence that it is known in the art to construct Petri dishes out of polystyrene (See column 2, lines 66-70).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made employ a polystyrene culture dish for the known and expected result of providing an alternative means recognized in the art to achieve the same result, provide a culture dish for holding cells during cell culture and optical observation.

12. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masao et al.(JP 58-155087) in view of Bisconte (US 4,800,164).

The reference of Masao et al. has been discussed above.

With respect to claim 5, while the reference of Masao et al. disclose a optical observation device (14), the reference is silent with respect to the use of a camera.

The reference of Bisconte discloses that it is conventional in the art to employ a CCD camera and imager (See column 4, lines 30-33; and column 8, lines 59-62) when optically interrogating culture vessels (4) within an incubation device (3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a camera and imaging device in the system of the primary reference of Masao et al. for the known and expected result of digitizing the culture vessel contents as is conventional in the art as evidenced by the reference of Bisconte.

With respect to the camera moving means of claim 6, the reference of Bisconte discloses relative movement of the imager and plate (See column 8, lines 35-53) for imaging a low magnification field under high magnification. Whether the relative movement is made using a device for moving the culture vessel or the imaging device would have been merely an obvious matter in design choice while providing the required relative movement for scanning the contents of the culture vessel.

With respect to the memory means of claim 7, if not inherent within the system of the modified primary reference discussed above, it would have been obvious to one of ordinary skill in the art to provide a memory means as recited in claim 7 for the known and expected result of saving the position of detected cells within a culture vessel.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masao et al.(JP 58-155087) in view of Vaillancourt (US 5,637,107).

The reference of Masao et al. has been discussed above.

Claim 8 differs by reciting the use of a vessel with a sealed blocking member and a thin tube for insertion into the tube.

The reference of Vaillancourt discloses that it is known in the art to communicate a thin tube (20) with the interior of a vessel (10) using a blocking member (12) including bactericide (15).

In view of this teaching, it would have been obvious communicate tubes (76) of the reference of Masao et al. with vessels (74) in a manner as disclosed by the reference of Vaillancourt for the known and expected result maintaining the sterility of the culture system when replacing the vessels within the system. The vessels (74) of the primary reference are structurally capable of holding cells.

14. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masao et al.(JP 58-155087) in view of Cannon et al.(US 7,270,996)

The reference of Masao et al. has been discussed above.

Claims 11 and 12 differ by reciting that the culture device includes waste lines and pH detection devices.

The reference of Cannon et al. discloses that it is known in the art to detect the pH of waste liquid flowing from a culture vessel (10) using an optical detection device in the waste flow line (See Figure 8; column 9, lines 31-35; and column 8, lines 6-20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to monitor the pH of the liquid waste from the culture vessel (4) of the primary reference for the



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known and expected result of monitor and control of the cell culture conditions as is conventional in the art as evidenced by the reference of Cannon et al.

***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael A. Marcheschi, can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/  
Primary Examiner  
Art Unit 1797**

WHB

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